

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

EXERGEN CORPORATION

Plaintiff,

V.

KAZ USA, INC.

Defendant.

Civil Action No. 1:13-cv-10628-RGS

**REDACTED COPY
FOR PUBLIC FILING**

**DECLARATION OF FRANCESCO POMPEI, Ph.D.
IN OPPOSITION TO KAZ USA, INC.'S
MOTIONS FOR SUMMARY JUDGMENT**

I, Francesco Pompei, declare as follows:

1. I am a founder and the CEO of Exergen Corporation and have been since 1980. Exergen makes and sells infrared thermometers, including infrared ear thermometers and infrared forehead thermometers. My role at Exergen is broad and includes technical work (e.g., designing and testing thermometers, including infrared ear and forehead thermometers) and management work (e.g., running Exergen's thermometer business). These statements are based on my personal knowledge.

2. A true and correct copy of my CV is attached hereto as Exhibit 1.

3. I hold B.S. and M.S. degrees from the Massachusetts Institute of Technology in mechanical engineering and an S.M. and a Ph.D. from Harvard University in engineering sciences.

4. I founded Exergen in 1980, after spending several years consulting on energy and heat loss in industrial and commercial settings. Since that time I have worked in the field of

thermometry, and specifically the determination of body temperature in humans. Through that work, I have become familiar with the level of skill of one of ordinary skill in the field.

5. I am a named inventor on many patents issued by the United States Patent and Trademark Office, including the patents in suit, U.S. Pat. Nos. 6,292,685 (“the ‘685 Patent”) and 7,787,938 (“the ‘938 Patent”). I am also the named inventor on U.S. Pat. No. 5,012,813 (“the ‘813 Patent”), and I designed the DermaTemp surface scanning thermometer.

6. I devoted many years to research and development of infrared thermometry before applying in September 1998 for patent protection for forehead thermometry methods and devices. The ‘685 and ‘938 Patents issued from or claim priority to that application.

7. I spent years promoting clinical trials of Exergen’s forehead thermometer to overcome skepticism in the medical community regarding the methods of thermometry claimed in the ‘938 Patent. Exergen has grown into a successful business thanks to its manufacture and sales of patented infrared forehead thermometers.

8. Prior to completing these trials, I encountered widespread skepticism among doctors, nurses and other health professionals, who initially believed that measuring temperature at the forehead could not lead to accurate reporting of core body temperature. Specifically, I heard those in the field express the opinion that the forehead was too exposed to the environment, and thus subject to too much variation in temperature through heat loss to the environment, to provide measurements that could allow accurate determination of core body temperature. It took many years of performing clinical trials and educating the field about the Exergen thermometer to overcome this skepticism.

9. At the time of the invention, exposed body sites, such as the forehead, were not considered appropriate sites for measurement, both because of the difference in temperature

between such sites and the body temperature, and because the exposure to ambient temperature was considered to cause too much variation in temperatures measured at such sites.

10. As I explained to the examiner during prosecution of the '938 Patent, in an effort to provide a less invasive thermometer of high accuracy, Exergen developed, in the late 80's, an ear thermometer exemplified by the '813 and '238 patents. The ear was selected because it provided a thermally protected region relative to axillary and forehead. Techniques utilized for improved accuracy included scanning of the ear by pivoting the device with peak temperature detection and a heat balance approach that used a constant, in a thermal resistance model between core temperature and ambient, to provide an approximation of internal temperature. Because the ear technique was not sufficiently non-invasive, an axillary approach was attempted. In that approach, the model was improved to include perfusion.

11. In yet a further effort to provide a non-invasive, high accuracy temperature measurement, Exergen developed the temporal artery technique presented in the '938 Patent. Prior to the invention, a high accuracy temporal artery thermometer had not been available due to exposure to varying ambient temperatures. The successful development is based on a number of elements presented in various claims of the '938 Patent. Further, it was determined that the heat balance approach could be extended to arterial heat balance to provide an accurate approximation of a body temperature, other than that of skin surface, despite the open exposure to ambient.

12. In addition, there is a distinction between the conventional use of ambient temperature in a radiometer calculation to provide an accurate surface temperature and the further use by Exergen of ambient temperature in a physiological computation to provide an approximation of a temperature other than skin surface temperature.

13. The mere existence of the heat flow models disclosed in the '813 and '238 patents would not have led those in the art to apply the measurement techniques disclosed in those patents to the forehead. Compensating for ambient temperature in connection with measuring temperatures in humans is not as old as thermometry, and was not at the time of the invention part of all heat-flow measurements.

14. Exergen's thermometers have been a commercial success in the U.S. and throughout the world. Exergen has sold approximately [REDACTED] TAT-2000C consumer devices in the U.S. With respect to professional devices, Exergen had sold [REDACTED] of the TAT-5000 model and [REDACTED] of the TAT-2000 in the U.S. Exergen grew into a successful business because of its manufacture and sale of patented infrared forehead thermometers.

15. Exergen is not a large conglomerate that makes a variety of household or medical care products that are routinely bought by customers.

16. Consumers recommend Exergen's product to one another and medical professionals recommend them to consumers. *See, e.g.*, Ex. E48¹ (a true and correct copy of a 2008 consumer letter to Exergen indicating that Exergen's "TemporalScanner 2000C is great [and] honestly ... much better than the ear thermometer ... I tell all my friends about it and now they all plan on purchasing one too"); Ex. E49 (a true and correct copy of a 2006 consumer email to Exergen; "I recently bought one of your new temporal units at Wal-Mart for my grandson and it is outstanding!"); Ex. E50 (a true and correct copy of a 2007 consumer email to Exergen regarding her "new temporal scanner," which she characterizes as a "wonderful product," noting "I will continue to recommend it to all of my friends and family, especially anyone with children.

¹ References to lettered exhibits are to exhibits attached to the Declaration of Stephen Underwood in Support of Kaz's Summary Judgment Motions. References to exhibits numbered E01-E83 are to exhibits attached the Declaration of Brandon Scruggs in Opposition to Kaz's Summary Judgment Motions, filed herewith.

(Everyone knows how hard it is to take a child's temperature 'the old fashioned way', and the temporal artery scanner answered a LOT of little prayers ..."); Ex. E51 (a true and correct copy of a posting on a public website by an expectant mother writes that she bought Exergen's temporal artery thermometer after a nurse teaching child care classes informed her that ear thermometers were "dangerous because the [sic] could hurt the baby's eardrum," but "this great thermometer that Exergen Corp was manufacturing" was "awesome" and "worth every single penny" even though it was more expensive than regular thermometers, also noting two 5-star ratings on the babiesrus.com web site; dated 2002).

17. Exergen's products embodying/practicing the Patents-in-Suit have been copied by others in the marketplace since they were first introduced by Exergen. Exergen has sued the makers/sellers/suppliers of several other temporal artery thermometers for patent infringement. For example, Exergen sued the following companies:

a. **SAAT and Daiwa.** Exergen sued SAAT and Daiwa for patent infringement of several Exergen patents, including the '685 Patent, one of the Patents-in-Suit. The accused devices in this case were infrared forehead scanning thermometers that provided a body temperature approximation. Exergen won this case in a jury trial, but lost on some issues on appeal.

b. **Kidz-Med, ASR, Tecnimed.** In 2008, Exergen sued Kidz-Med, ASR, and Tecnimed, over infrared forehead thermometers (that provide a body temperature approximation) such as the Thermofocus thermometer, for infringing five of Exergen's patents. This case is still pending in court.

c. **SDI Diagnostics.** In August 2011, Exergen sued SDI, the seller of the ASTRATEMP and TRUTEMP infrared forehead thermometers (that provide body

temperature approximations), for infringement of the '938 Patent, one of the Patents-in-Suit. SDI Diagnostics voluntarily withdrew its products from the market.

d. **Advanced Diagnostics Corporation (ADC).** Exergen sued ADC, the supplier of the Adtemp 428 Non Contact Infrared Thermometer (which was an infrared forehead thermometer that provided a body temperature approximation), for infringement of the '685 Patent and the '938 Patent. In October 2012, after Exergen filed the lawsuit, that ADC voluntarily withdrew its product from the market.

e. **Brooklands.** In December 2012, Exergen filed suit against Brooklands, Inc., the supplier of the VeraTemp and VeraTemp+ infrared forehead thermometers (that provide body temperature approximations), for infringement of the '938 Patent, one of the Patents-in-Suit. This case is still pending in court. Brooklands supplies the infrared forehead thermometers sold under the store brand at CVS and Walgreens.

f. **Thermomedics and Sanomedics.** In May 2013, Exergen filed suit against Thermomedics and Sanomedics, the suppliers of the CareGiver and other infrared forehead thermometers (that provide body temperature approximations), for infringement of the '938 Patent, one of the Patents-in-Suit. This case is still pending in court.

18. Other companies in the thermometry field have sought a license to Exergen's patents, including the Patents-in-Suit. There have been regular requests for a license by many of those in the thermometry field for Exergen's thermometry patents. For example, in 2009, TaiDoc Technology Corporation requested a license from Exergen for the '685 Patent, which it described as "a patent ... measuring the temporal temp for forehead thermometer." Ex. E52 (a true and correct copy of the request). Exergen declined to grant a license to TaiDoc. Ex. E53 (a true and correct copy of Exergen's correspondence declining request from Microlife for license

to Exergen's infrared medical thermometry technology). Kaz asked Exergen for a license to Exergen's thermometry technology in July 2005. Ex. E22 is a true and correct copy of the email chain with this request, and Exergen's response. On July 28, 2005, Bob Cullen, who was President of Kaz, Inc. at the time, sent an email to Marybeth Pompei of Exergen. *Id.* Mr. Cullen indicated that Kaz competes in the "thermometry" market and for this reason was contacting Exergen. *Id.* Mr. Cullen congratulated Exergen on the "outcome of [Exergen's] patent case with SAAT and Daiwa." *Id.* I understand that in that case the jury found infringement of Exergen's '685 Patent, which is one of the Patents-in-Suit. Mr. Cullen then writes: "it reminded me that several years ago [Kaz's] CEO contacted Exergen to see if there was interest in licensing [Exergen's] technology to Kaz and marketing it under the Vicks brand. I think the answer at the time was that Exergen had its own plans to go forward without a partner and that was that. I thought I would drop you a note to revisit the issue of licensing the Exergen technology. My thought is perhaps now is the time to bring out a second brand to more fully develop the category. We would propose paying a license fee to Exergen ... and marketing under the Vicks name." *Id.* I responded by email on July 28, 2005. *Id.* I wrote that Exergen was "flattered ... by the regular requests for a license by Kaz, and by essentially everyone else in the thermometry field as well. However, our answer is the same as it has been. Exergen is not interested in licensing its patents in this field..." *Id.*

19. Exergen's general policy with respect to the Patents-in-Suit is that Exergen does not license them. However, Exergen has entered into a supply and distribution agreement with GE Medical Systems Information Technologies, Inc. ("GE Healthcare"), dated July 2007. Ex. E54. That agreement states that "[REDACTED]"

[REDACTED]

██████████
██████████” *Id.*

20. Exergen has received numerous awards and accolades for its forehead thermometer technology. For example, in 2002, the Exergen TemporalScanner temporal artery thermometer was awarded the 16th Annual New England Innovation Award by the Smaller Business Association of New England (SBANE). Ex. E55 and Ex. E56 are true and correct copies of press releases referencing the award. In a segment on the Today Show in July 2001, Dr. Mark Widdome, of the American Academy of Pediatrics praised the Exergen Temporal Artery Thermometer as “rocket science.” In 2002, *Working Mother Magazine* called the device “the magic wand you’ve been waiting for.” Ex. E57 (a true and correct copy of excerpts from that magazine; under the heading “Cool Tools: High-Tech First Aid for Your Home”). In 2009, *Inc. Magazine* named Exergen’s temporal artery thermometer device one of the 24 “Smartest Products of the Decade.” Ex. 58 is true and correct copy of a press release referencing the award, and Ex. E58 and Ex. E59 are features from Inc.com about the award. Other awards that Exergen’s temporal artery thermometer received include the Greater Boston Chamber of Commerce Award in 2006, and the 2009-10 Most Valuable Product Award by a nursing organization. Ex. E56, (a true and correct copy of a press release referencing the award).

21. Exergen has also received private praise from medical professionals, including notes from school nurses and correspondence indicating that professionals recommend the Exergen temporal artery thermometer. *See, e.g.*, Ex. E60 (a true and correct copy of a 2006 email from school nurse to Exergen indicating her school has been using the Exergen TAT2000 in school clinics, she has parents contacting her to find out what they use and where they can find the TAT2000, noting the product has been a “blessing for my clinic ... no longer a fight to

get an accurate temp and takes no time at all. Thanks for the great product, we plan to continue to use them in all seven of our county schools”); Ex. E61 (a true and correct copy of correspondence from an expectant mother writes that she bought Exergen’s temporal artery thermometer after a nurse teaching child care classes informed her that ear thermometers were “dangerous because the [sic] could hurt the baby’s eardrum,” but “this great thermometer that Exergen Corp was manufacturing” was “awesome” and “worth every single penny” even though it was more expensive than regular thermometers, also noting two 5-star ratings on the babiesrus.com web site; dated 2002); Ex. E62, (doctor at St. Vincent hospital writes to Exergen in 2006, indicating he “received the new temporal artery thermometers” from Exergen and “We are very excited about this new technology ... Please let us know how we can help your company spread the use of this wonderful technology”); Ex. E63 (a true and correct copy of a 2006 email from Nurse Manager at Gillette Children’s Hospital indicating she received the Exergen TAT-2000C model; the “wonderful thing is that ... the threat of infectious disease ... will be minimized. ... I will continue to promote your product.”).

22. Exergen has also received positive online reviews. *See, e.g.*, Ex. E64, (a true and correct copy of Walmart online rating from 2009 indicating 199 five-star reviews and 47 four-star reviews out of 268 total reviews; comments praise temporal artery thermometer for being non-invasive, easy to use on children or the elderly [even when sleeping], fast, accurate, clean; some reviewers self-identify as nurses).

23. I am familiar with the Thermoscan License, Ex. HHH, because I was President at Exergen when Exergen entered into that agreement with Thermoscan, Inc. I was personally involved in negotiating and reviewing the Thermoscan License before execution. I signed the Thermoscan License on behalf of Exergen.

24. I am familiar with Article II of the Thermoscan License, in which Exergen granted Thermoscan, Inc. a non-exclusive license to make, use, sell and to have made all goods, and to practice all methods covered by each and every Licensed Patent in the Licensed Field.

25. I am familiar with the definition of “Licensed Field” in Article I.C. of the Thermoscan License, which states:

The “Licensed Field” shall mean the field of electronic or electromechanical instruments for measuring any temperature characterizing a living person or animal employing any transducer whatever, except for instruments employing an Excepted Transducer. Disposable probe covers for such instruments are expressly excluded from the Licensed Field, except as provided in Article VI, Section C.

26. I am familiar with the definition of “Excepted Transducer” in Article I.B. of the Thermoscan License, which states:

“Excepted Transducer” shall mean a heat responsive device with two open leads electrically interfaced to a number of serially connected junctions called a thermopile where each junction is called a thermocouple, and where a thermocouple is a device which converts a temperature difference into an electromotive force called a Seebeck voltage, and such voltage persists as long as the temperature difference persists.

27. I am familiar with Article VII.H. of the Thermoscan License, which states:

If the relative economic or technical attractiveness of Excepted Transducers materially changes from the circumstances existent at the time of execution of this Agreement such that it is no longer practicable for Thermoscan to market the product without an Excepted Transducer, then the restriction in the license of Article II from using an Excepted Transducer shall not apply to Exergen’s ambient compensation invention, claimed in claims 1-5 of said U.S. Letters Patent No. 5,199,436, claims 7-8 of U.S. Letters Patent No. 5,012,813, and claim 23 of U.S. Letters Patent No. 4,993,419, and any claims of corresponding scope in any foreign counterparts, continuations, divisions, reissues, or reexaminations thereof.

28. In August 1993, Thermoscan made infrared ear thermometers. At that time, Thermoscan’s products did not use thermopiles, they used pyroelectric infrared sensors. At that time, Exergen’s ear thermometers did use thermopiles.

29. At the time Exergen entered into the Thermoscan License (August 12, 1993), Exergen’s intent was to exclude thermometers employing thermopiles from the scope of the

license grant to Thermoscan, except under the narrow conditions and circumstances set forth in Article VII.H.


30. I have been and am familiar with the relative economic and technical attractiveness of thermopiles in thermometers, including in the period from the 1980s to the present. I am familiar with the technical attractiveness of thermopiles because of my technical education and experience designing thermometers for Exergen. I am familiar with the economic attractiveness of thermopiles through my business experience with Exergen.

31. The relative economic or technical attractiveness of thermopiles did not materially change from the circumstances on August 12, 1993.

32. This is consistent with my May 10, 2007 letter to Richard Katzman at Kaz: “Exergen does not concur that the Excepted Transducer restriction exception of Article VII(H) that you claim, applies.”

I declare under the penalties of perjury that the foregoing is true and correct.

Dated: June 16, 2015

A handwritten signature in blue ink, appearing to read "Pompei, Ph.D.", is written above a horizontal line.

Francesco Pompei, Ph.D.

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) on June 16, 2015.

/s/ Kerry L. Timbers

Kerry L. Timbers